DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 4, 2014

BIOPLAX Limited
c/o Mr. Paul Ketteridge
PD Regulatory Consulting, LLC
472 S State Street, Unit 101
Bellingham, WA 98225

Re: K130959
Trade/Device Name: Aftamed® Mouthwash, Aftamed™ Gel, _Aftamed® Spray, Aftamed® Shield, Aftamed™ Junior Gel
Regulation Number: Unclassified
Regulation Name: Dressing, Wound and Burn, Hydrogel with Drug and/or Biologic
Regulatory Class: Unclassified
Product Code: MGQ
Dated: December 30, 2013
Received: January 6, 2014

Dear Mr. Ketteridge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K130959
Response to Refuse to Accept (RTA)
November 18, 2013

Indications for Use- Aftamed Mouthwash

510(k) Number (if known): K130959

Device Name: Aftamed® Mouthwash

Indications for Use:

Aftamed® Mouthwash provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: aphthous ulcers caused by disease; traumatic ulcers caused by braces, ill-fitting dentures or oral surgery.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use **XXXX** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___ *(Posted November 13, 2003)*

Sheena A. Green -S
2014.04.04 11:25:54 -04'00'

Indications for Use- Aftamed Gel

510(k) Number (if known): K130959

Device Name: Aftamed™ Gel

Indications for Use:

Aftamed® Gel provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: aphthous ulcers caused by disease; traumatic ulcers caused by braces, ill-fitting dentures or oral surgery.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use XXXX (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___ *(Posted November 13, 2003)*

Sheena A. Green -S
2014.04.04 11:26:17
-04'00'

Indications for Use- Aftamed Spray

510(k) Number (if known): K130959

Device Name: _Aftamed® Spray

Indications for Use:

Aftamed® Spray provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: aphthous ulcers caused by disease; traumatic ulcers caused by braces, ill-fitting dentures or oral surgery

Prescription Use ____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use XXXX (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___ *(Posted November 13, 2003)*

Sheena A. Green -S
2014.04.04 11:26:39 -04'00'

Indications for Use- Aftamed Shield

510(k) Number (if known): K130959

Device Name: Aftamed® Shield

Indications for Use:

Aftamed® Shield provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: aphthous ulcers caused by disease; traumatic ulcers caused by braces, ill-fitting dentures or oral surgery.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use **XXXX**
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___ *(Posted November 13, 2003)*

Sheena A. Green -S
2014.04.04 11:27:00 -04'00'

Indications for Use- Junior Gel

510(k) Number (if known): K130959

Device Name: _Aftamed™ Junior Gel

Indications for Use:

Aftamed® Junior Gel provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: aphthous ulcers caused by disease; traumatic ulcers caused by braces, or oral surgery.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use XXXX (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___ *(Posted November 13, 2003)*

Sheena A. Green -S
2014.04.04 11:27:20 -04'00'

510(k) Summary- Aftamed Mouthwash

Date Summary Prepared: April 3, 2014

Applicants Name: BIOPLAX Limited
6th Floor
32 Ludgate Hill
EC4M 7DR London - UK

Contact Person: Paul Ketteridge, (Consultant to BIOPLAX)
472 S State Street Unit 101
Bellingham, WA 98225
443-729-0836
p.kett@pd-reg.com

Device Name: Aftamed® Mouthwash.
Classification Name: Dressing, Wound and Burn, Hydrogel w/Drug and/or Biologic
Product Code: MGQ
CFR Section: None
Device Class: Unclassified

Predicate Devices K053342
Gengigel Mouthwash
Ricerfarma Srl
Via Egadi, 7-20144
Milano, Italy
Product Code-MGQ

Device Description:

Aftamed® Mouthwash adheres to oral mucosa and forms a protective film over lesions and irritations due to various etiologies, including: aphthous ulcers caused by disease; traumatic ulcers caused by braces, ill-fitting dentures or oral surgery. The viscosity and adherence properties of the constituents of the device allow the device to form the protective film which protects the lesions for external insult.

Indications:

Aftamed® Mouthwash provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: aphthous ulcers caused by disease; traumatic ulcers caused by braces, ill-fitting dentures or oral surgery.

510(k) Summary- Aftamed Mouthwash (continued)
Date Summary Prepared: April 3, 2014

Non-Clinical Testing:

The following table details the specific tests and results performed on the Aftamed Mouthwash.

Test	Test Description	Results
Human Skin Irritation Test	ISO 10993-10	Minimal irritant
Cytotoxicity Evaluation	ISO 10993-5	Wholly devoid of cytotoxic/irritant effects on primary human fibroblasts
Sensitization	10-993-10	Does not show significant cytotoxic effects on fibroblasts as a whole

Non-Clinical Testing Conclusioin: These tests show that the product meets the required non-clinical testing requirements as detailed in the ISO 10993 guidance

Physical Testing

The following physical testing is performed on each lot of product to assure quality:

- Organoleptic characteristics
- Viscosity
- pH
- Density
- Mean weight of package contents:
- Microbe count

Substantial Equivalence:

In summary, the Aftamed Mouthwash and its predicate have identical indications and intended uses, are physically composed of very similar ingredients or ingredients which serve the same function. Both the Aftamed Mouthwash and its predicates share almost identical specifications, and their biocompatibility testing, both in the types of test performed, and its results are virtually identical. Therefore the Aftamed Mouthwash is substantially equivalent to its predicate.

Aftamed®
K130959

510(k) Summary- Aftamed Gel

Date Summary Prepared: April 3, 2014

Applicants Name:	BIOPLAX Limited 6th Floor 32 Ludgate Hill EC4M 7DR London - UK
Contact Person:	Paul Ketteridge, (Consultant to BIOPLAX) 472 S State Street Unit 101 Bellingham, WA 98225 443-729-0836 p.kett@pd-reg.com
Device Name:	Aftamed® Gel.
Classification Name:	Dressing, Wound and Burn, Hydrogel w/Drug and/or Biologic
Product Code:	MGQ
CFR Section:	None
Device Class:	Unclassified
Predicate Devices	K053342 Gengigel Gel Ricerfarma Srl Via Egadi, 7-20144 Milano, Italy Product Code-MGQ

Device Description:

Aftamed® Gel adheres to oral mucosa and forms a protective film over lesions and irritations due to various etiologies, including: aphthous ulcers caused by disease; traumatic ulcers caused by braces, ill-fitting dentures or oral surgery. The viscosity and adherence properties of the constituents of the device allow the device to form the protective film which protects the lesions for external insult.

Indications:

Aftamed® Gel provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: aphthous ulcers caused by disease; traumatic ulcers caused by braces, ill-fitting dentures or oral surgery.

510(k) Summary- Aftamed Gel (continued)
Date Summary Prepared: April 3, 2014

Non-Clinical Testing:

The following table details the specific tests and results performed on the Aftamed Gel.

Test	Test Description	Results
Irritation Test	ISO 10993-10	Minimal irritant compared to control
Cytotoxicity Evaluation	ISO 10993-5	Wholly devoid of cytotoxic/irritant effects on primary human fibroblasts
Guinea Pig Maximization Test	ISO 10993-10 Mag	Not sensitizing

Non-Clinical Testing Conclusioin: These tests show that the product meets the required non-clinical testing requirements as detailed in the ISO 10993 guidance

Physical Testing

The following physical testing is performed on each lot of product to assure quality:

- Organoleptic characteristics
- Viscosity
- pH
- Density
- Mean weight of package contents:
- Microbe count

Substantial Equivalence:

In summary, the Aftamed Gel and its predicate have identical indications and intended uses, are physically composed of very similar ingredients or ingredients which serve the same function. Both the Aftamed Gel and its predicates share almost identical specifications, and their biocompatibility testing, both in the types of test performed, and its results are virtually identical. Therefore the Aftamed Gel is substantially equivalent to its predicate.

Aftamed®
K130959

510(k) Summary- Aftamed Spray

Date Summary Prepared: April 3, 2014

Applicants Name:	BIOPLAX Limited 6th Floor 32 Ludgate Hill EC4M 7DR London - UK
Contact Person:	Paul Ketteridge, (Consultant to BIOPLAX) 472 S State Street Unit 101 Bellingham, WA 98225 443-729-0836 p.kett@pd-reg.com
Device Name:	Aftamed® Spray.
Classification Name:	Dressing, Wound and Burn, Hydrogel w/Drug and/or Biologic
Product Code:	MGQ
CFR Section:	None
Device Class:	Unclassified
Predicate Devices	K053342 Gengigel Spray Ricerfarma Srl Via Egadi, 7-20144 Milano, Italy Product Code-MGQ

Device Description:

Aftamed® Spray adheres to oral mucosa and forms a protective film over lesions and irritations due to various etiologies, including: aphthous ulcers caused by disease; traumatic ulcers caused by braces, ill-fitting dentures or oral surgery. The viscosity and adherence properties of the constituents of the device allow the device to form the protective film which protects the lesions for external insult.

Indications:

Aftamed® Spray provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: aphthous ulcers caused by disease; traumatic ulcers caused by braces, ill-fitting dentures or oral surgery.

510(k) Summary- Aftamed Spray (continued)
Date Summary Prepared: April 3, 2014

Non-Clinical Testing:

The following table details the specific tests and results performed on the Aftamed Spray.

Test	Test Description	Results
Human Skin Irritation Test	ISO 10993-10	Non-irritant
Cytotoxicity Evaluation	ISO 10993-5	Did not cause cytotoxic effects at all tested concentrations on fibroblasts
Sensitization	ISO 10993-10	Not Sensitizing

Non-Clinical Testing Conclusioin: These tests show that the product meets the required non-clinical testing requirements as detailed in the ISO 10993 guidance

Physical Testing

The following physical testing is performed on each lot of product to assure quality:

- Organoleptic characteristics
- Viscosity
- pH
- Density
- Mean weight of package contents:
- Microbe count

Substantial Equivalence:

In summary, the Aftamed Spray and its predicate have identical indications and intended uses, are physically composed of very similar ingredients or ingredients which serve the same function. Both the Aftamed Spray and its predicates share almost identical specifications, and their biocompatibility testing, both in the types of test performed, and its results are virtually identical. Therefore the Aftamed Spray is substantially equivalent to its predicate.

Aftamed®
K130959

510(k) Summary- Aftamed Shield

Date Summary Prepared: April 3, 2014

Applicants Name:	BIOPLAX Limited 6th Floor 32 Ludgate Hill EC4M 7DR London - UK
Contact Person:	Paul Ketteridge, (Consultant to BIOPLAX) 472 S State Street Unit 101 Bellingham, WA 98225 443-729-0836 p.kett@pd-reg.com
Device Name:	Aftamed® Shield.
Classification Name:	Dressing, Wound and Burn, Hydrogel w/Drug and/or Biologic
Product Code:	MGQ
CFR Section:	None
Device Class:	Unclassified
Predicate Devices	K053342 Gengigel Gel Ricerfarma Srl Via Egadi, 7-20144 Milano, Italy Product Code-MGQ

Device Description:

Aftamed® Shield adheres to oral mucosa and forms a protective film over lesions and irritations due to various etiologies, including: aphthous ulcers caused by disease; traumatic ulcers caused by braces, ill-fitting dentures or oral surgery. The viscosity and adherence properties of the constituents of the device allow the device to form the protective film which protects the lesions for external insult.

Indications:

Aftamed® Shield provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: aphthous ulcers caused by disease; traumatic ulcers caused by braces, ill-fitting dentures or oral surgery.

510(k) Summary- Aftamed Shield (continued)
Date Summary Prepared: April 3, 2014

Non-Clinical Testing:

The following table details the specific tests and results performed on the Aftamed Shield,

Test	Test Description	Results
In Vitro Assessment of Irritation Potential on EpiGingival™ Tissue Model	Classify according to its effect on cell viability after topical application on 3D models similar to gingival mucosa	Mild/non-irritant
Cytotoxicity Evaluation	ISO 10993-5	Did not show significant cytotoxic effects on fibroblasts as a whole
In Vitro Assessment of Sensitizing Potential on cell line THP-1.	THP-1 cell line	Is not considered as a suspect allergen
In vitro evaluation of protective effect of Aftamed Shield on oral epithelium	Cytotoxicity test, cell survival assay following SLS-induced irritating stress	Shows epithelium barrier protective and repairing activity following surfactant-induced irritating stress

Non-Clinical Testing Conclusioin: These tests show that the product meets the required non-clinical testing requirements as detailed in the ISO 10993 guidance

Physical Testing

The following physical testing is performed on each lot of product to assure quality:

- Organoleptic characteristics
- Viscosity
- pH
- Density
- Mean weight of package contents:
- Microbe count

Substantial Equivalence:

In summary, the Aftamed Shield and its predicate have identical indications and intended uses, are physically composed of very similar ingredients or ingredients which serve the same function. Both the Aftamed Shield and its predicates share almost identical specifications, and their biocompatibility testing, both in the types of test performed, and its results are virtually identical. Therefore the Aftamed Shield is substantially equivalent to its predicate.

Aftamed®
K130959

510(k) Summary- Aftamed Junior Gel

Date Summary Prepared: April 3, 2014

Applicants Name:	BIOPLAX Limited 6th Floor 32 Ludgate Hill EC4M 7DR London - UK
Contact Person:	Paul Ketteridge, (Consultant to BIOPLAX) 472 S State Street Unit 101 Bellingham, WA 98225 443-729-0836 p.kett@pd-reg.com
Device Name:	Aftamed® Junior Gel.
Classification Name:	Dressing, Wound and Burn, Hydrogel w/Drug and/or Biologic
Product Code:	MGQ
CFR Section:	None
Device Class:	Unclassified
Predicate Devices	K053342 Gengigel Junior Gel Ricerfarma Srl Via Egadi, 7-20144 Milano, Italy Product Code-MGQ

Device Description:

Aftamed® Junior Gel adheres to oral mucosa and forms a protective film over lesions and irritations due to various etiologies, including: aphthous ulcers caused by disease; traumatic ulcers caused by braces, ill-fitting dentures or oral surgery. The viscosity and adherence properties of the constituents of the device allow the device to form the protective film which protects the lesions for external insult.

Indications:

Aftamed® Junior Gel provides temporary pain relief by adhering to the oral mucosa and forming a protective film over lesions and irritations due to various etiologies, including: aphthous ulcers caused by disease; traumatic ulcers caused by braces, or oral surgery.

510(k) Summary- Aftamed Junior Gel (con't)
Date Summary Prepared: April 3, 2014

Non-Clinical Testing:

The following table details the specific tests and results performed on the Aftamed Junior Gel.

Test	Test Description	Results
Irritation Test	ISO 10993-10	Showed minimal irritant reaction compared with the negative control
Cytotoxicity Evaluation	ISO 10993-5	Did not show significant cytotoxic effects on fibroblasts as a whole
Sensitization	ISO 10993-10	Not sensitizing

Non-Clinical Testing Conclusioin: These test show that the product meets the required non-clinical testing requirements as detailed in the ISO 10993 guidance

Physical Testing

The following physical testing is performed on each lot of product to assure quality:

- Organoleptic characteristics
- Viscosity
- pH
- Density
- Mean weight of package contents:
- Microbe count

Substantial Equivalence:

In summary, the Aftamed Junior Gel and its predicate have identical indications and intended uses, are physically composed of very similar ingredients or ingredients which serve the same function. Both the Aftamed Junior Gel and its predicates share almost identical specifications, and their biocompatibility testing, both in the types of test performed, and its results are virtually identical. Therefore the Aftamed Junior Gel is substantially equivalent to its predicate.